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PATENT

Attorney Docket No. HOGAN-06550

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kirk Hogan

Serial No.: 09/976,423

Filed: 10/21/2001

Group No.: 1634

Examiner: J.E. Goldberg

Entitled: **Methods and Compositions for Perioperative Genomic Profiling**

**RESPONSE AND AMENDMENT TO THE OFFICE  
ACTION MAILED DECEMBER 2, 2002**

Assistant Commissioner for Patents  
Washington, D.C. 20231

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. § 1.8(a)(1)(i)(B)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

DATE - JAN. 2, 2003

By:

Mary Ellen Waite

Dear Examiner:

The following communication is response the Office Action mailed December 2, 2002 in the above-referenced application. As the pending Office Action set a one month shortened statutory period for Applicants' response, Applicants believe that the instant communication is timely filed and that no fees are due with its transmission. The Commissioner is, however, hereby authorized to charge any required fees to Attorney Deposit Account No. 08-1290 referencing Attorney Docket No.: HOGAN -06550.

In the Claims, please cancel Claims 1-23, and add the following Claims:

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AI 24. A kit for generating a perioperative genomic profile for a subject, comprising:

- a) reagents capable of detecting the presence of variant alleles of two or more genes selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$* ; and
- b) instructions for using said kit for generating said perioperative genomic profile for said subject.

25. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate general anesthesia treatment course of action.

26. The kit of Claim 25, wherein said general anesthesia is an inhalational treatment course of action.

27. The kit of Claim 25, wherein said general anesthesia is an intravenous treatment course of action.

28. The kit of Claim 25, wherein said general anesthesia is a combined inhalational and intravenous treatment course of action.

29. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate regional anesthesia treatment course of action.

30. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate combined regional and general treatment course of action.

31. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate non-invasive surgery treatment course of action.

32. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate invasive surgery treatment course of action.

33. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate anesthesia treatment course of action during a medical procedure.

34. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting appropriate dosages of analgesic compounds.

35. The kit of Claim 30, wherein said instructions describe that said perioperative genomic profile is consulted to increase the dosage of analgesic compounds metabolized by CYP2D6.

36. The kit of Claim 30, wherein said instructions describe that said perioperative genomic profile is consulted to decrease the dosage of analgesic compounds metabolized by CYP2D6.

37. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting appropriate prophylaxis for thrombosis.

38. The kit of Claim 33, wherein said instructions describe that said perioperative genomic profile is consulted to increase prophylaxis for thrombosis mediated by variant alleles of *F5*, *F2*, *MTHFR*, *MTR*, *MTRR*, and *CBS*.

39. The kit of Claim 33, wherein said instructions describe that said perioperative genomic profile is consulted to decrease prophylaxis for thrombosis mediated by variant alleles of *F5*, *F2*, *MTHFR*, *MTR*, *MTRR*, and *CBS*.

40. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting appropriate monitoring procedures.

41. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting pre-operative phenotypic tests and consultations.

42. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in providing a prognosis after an anesthesia treatment course of action.

43. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in providing a prognosis after a surgical treatment course of action.

44. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate post-operative treatment course of action.

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## REMARKS

Claims 1-23 are pending and under examination. In the Office Action mailed December 2, 2002 the Examiner made a Restriction Requirement, restricting pending claims 1-23 into the following groups: Group I (claims 1-21) drawn to methods of screening a patient perioperatively to determine a risk for surgical complications by obtaining a sample from a perioperative subject and detecting variant alleles in two or more genes to generate a genomic profile, classified in class 435, subclass 6; Group II (claim 22) drawn to a kit comprising a reagent capable of detecting the presence of a variant allele of two or more markers and instructions, classified in class 536, subclass 23.1; and Group III (claim 23) drawn to a perioperative genomic profile comprising information, classified in class 702, subclass 27.

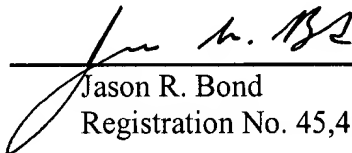
Applicant elects, without traverse, to prosecute the claims of Group II. Applicant reserves the right to prosecute the claims of Groups I and III in one or more divisional applications.

In an Amendment accompanying this response, Applicant has cancelled Claims 1-23, and added Claims 24-44, which are directed to the subject matter of group II. A copy of all pending Claims is attached hereto for the Examiner's convenience.

## CONCLUSION

Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 1/2/03

  
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Jason R. Bond  
Registration No. 45,439

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San Francisco, California 94105

## PENDING CLAIMS

24. A kit for generating a perioperative genomic profile for a subject, comprising:
- c) reagents capable of detecting the presence of variant alleles of two or more genes selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$* ; and
  - d) instructions for using said kit for generating said perioperative genomic profile for said subject.
25. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate general anesthesia treatment course of action.
26. The kit of Claim 25, wherein said general anesthesia is an inhalational treatment course of action.
27. The kit of Claim 25, wherein said general anesthesia is an intravenous treatment course of action.
28. The kit of Claim 25, wherein said general anesthesia is a combined inhalational and intravenous treatment course of action.
29. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate regional anesthesia treatment course of action.
30. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate combined regional and general treatment course of action.

31. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate non-invasive surgery treatment course of action.

32. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate invasive surgery treatment course of action.

33. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate anesthesia treatment course of action during a medical procedure.

34. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting appropriate dosages of analgesic compounds.

35. The kit of Claim 30, wherein said instructions describe that said perioperative genomic profile is consulted to increase the dosage of analgesic compounds metabolized by CYP2D6.

36. The kit of Claim 30, wherein said instructions describe that said perioperative genomic profile is consulted to decrease the dosage of analgesic compounds metabolized by CYP2D6.

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42. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in providing a prognosis after an anesthesia treatment course of action.

43. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in providing a prognosis after a surgical treatment course of action.

44. The kit of Claim 24, wherein said instructions describe that said perioperative genomic profile is consulted in selecting an appropriate post-operative treatment course of action.